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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/630,401	07/30/2003	Brett P. Monia	ISPH-0754	5448

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Licata & Tyrrell P.C.
66 E. Main Street
Marlton, NJ 08053

EXAMINER	
VIVLEMORE, TRACY ANN	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 02/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/630,401	MONIA ET AL.	
	Examiner	Art Unit	
	Tracy Vivlemore	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 4-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2 and 4-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7/30/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 11 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

1. Claim 11 is directed to a compound 8-50 nucleobases in length that hybridizes with at least 8 nucleobases of a nucleic acid molecule encoding fibroblast growth factor receptor 3 (FGFR3). This claim encompasses any sequence complementary to 8 bases or more of a nucleic acid encoding FGFR3 from any species. The breadth of this claim is such that it constitutes a large genus of compounds that comprise any sequence up to 50 nucleobases in length that need share complementarity with only 8 nucleobases of FGFR3. This includes not only antisense sequences but also probes and primers.

2. The specification teaches numerous antisense sequences to human FGFR3 demonstrated to inhibit expression of human FGFR3 (as shown in Table 1). The specification does not describe any antisense sequences or probes or primers that

would hybridize to at least 8 nucleobases of FGFR3 from any other species. There is no structure disclosed in the specification or known in the art that would correspond to the function of hybridizing to at least 8 nucleobases of an FGFR3 from any species other than humans.

3. Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

4. MPEP 2163 states in part, "An adequate written description of a chemical invention also requires a precise definition, such as by structure, formula, chemical name, or physical properties, and not merely a wish or plan for obtaining the chemical invention claimed. See, e.g., *Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 927, 69 USPQ2d 1886, 1894-95 (Fed. Cir. 2004) (The patent at issue claimed a method of selectively inhibiting PGHS-2 activity by administering a non-steroidal compound that selectively inhibits activity of the PGHS-2 gene product, however the patent did not disclose any compounds that can be used in the claimed methods. While there was a description of assays for screening compounds to identify those that inhibit the expression or activity of the PGHS-2 gene product, there was no disclosure of which peptides, polynucleotides, and small organic molecules selectively inhibit PGHS-2. The

court held that "[w]ithout such disclosure, the claimed methods cannot be said to have been described.")."

5. With the exception of antisense sequences directed to human FGFR3, the skilled artisan cannot envision the detailed structure of the encompassed genus of compounds that are partially complementary to FGFR3 from any other species, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

6. Therefore, only antisense sequences directed to the disclosed human gene, but not the full breadth of the claim meets the written description provision of 35 USC 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.)

Claim 15 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for inhibition of gene expression with antisense oligonucleotides in cells *in vitro*, does not reasonably provide enablement for antisense

inhibition of gene expression in cells or tissues *in vivo*. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The following factors as enumerated *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988), are considered when making a determination that a disclosure is not enabling: the breadth of the claims, the nature of the invention, the state of the prior art, the level of ordinary skill in the art, the level of predictability in the art, the amount of direction provided by the inventor, the existence of working examples and the quantity of experimentation needed to make the invention based on the content of the disclosure.

7. Claim 15 is drawn to a method of inhibiting expression of fibroblast growth factor receptor 3 in cells or tissues by contacting the cells with an antisense oligonucleotide. This claim encompasses both embodiments where the cells or tissue are in an organism as well as embodiments where the cells or tissues are not in an organism. The specification describes on pages 29-33 carriers for different types of delivery to organisms that can be used to formulate antisense oligonucleotides as therapeutic agents and routes of administration general to any therapeutic. The specification does not describe how to administer antisense oligonucleotides to any organism such that the oligonucleotide enters the cells of the organism in a sufficient concentration and remains active for a sufficient period to time to inhibit expression of fibroblast growth factor receptor 3.

8. The state of the art prior art is such that inhibition of gene expression *in vitro* is routine, but *in vivo* inhibition of gene expression at the time of filing and even to the present time is not routine for several reasons, including the problems of delivery, specificity and duration.

9. The problems of nucleic acid based therapies and antisense technology are well known in the art, particularly with regard to the inability to specifically deliver an effective concentration of a nucleic acid to a target cell, such that a target gene is inhibited to a degree necessary to result in a therapeutic effect. For example, at the time the instant invention was made, the therapeutic use of nucleic acids was a highly unpredictable art due to obstacles that continue to hinder the therapeutic application of nucleic acids *in vivo* (whole organism) (see for example Agrawal et al. (Molecular Medicine Today, 2000, vol 6, p 72-81), Jen et al. (Stem Cells 2000, Vol. 18, p 307-319) and Opalinska et al. (Nature Reviews Drug Discovery, 2002, vol 1, p. 503-514)). Such obstacles include, for example, problems with delivery, target accessibility and the potential for unpredictable nonspecific effects.

10. Jen et al. state (see page 313, second column, second paragraph) "One of the major limitations for the therapeutic use of AS-ODNS and ribozymes is the problem of delivery....presently, some success has been achieved in tissue culture, but efficient delivery for *in vivo* animal studies remains questionable". Jen et al. outlines many of the factors limiting the application of antisense for therapeutic purposes and concludes (see p 315, second column), "Given the state of the art, it is perhaps not surprising that effective and efficient clinical translation of the antisense strategy has proven elusive."

11. Opalinska et al. (Nature Reviews Drug Discovery, 2002, vol 1, p. 503-514) state "[I]t is widely appreciated that the ability of nucleic-acid molecules to modify gene expression *in vivo* is quite variable, and therefore wanting in terms of reliability. Several issues have been implicated as a root cause of this problem, including molecule delivery to targeted cells and specific compartments within cells and identification of sequence that is accessible to hybridization in the genomic DNA or RNA" and in column 2 of the same page, "Another problem in this field is the limited ability to deliver nucleic acids into cells and have them reach their target. Without this ability, it is clear that even an appropriately targeted sequence is not likely to be efficient. As a general rule, oligonucleotides are taken up primarily through a combination of adsorptive and fluid-phase endocytosis. After internalization, confocal and electron microscopy studies have indicated that the bulk of the oligonucleotides enter the endosome-lysosome compartment, in which most of the material becomes either trapped or degraded."

12. Given this unpredictability, the skilled artisan would require specific guidance to practice the claimed methods *in vivo* in all organisms, with a resultant inhibition of gene expression, as claimed. The specification provides examples of inhibition of fibroblast growth factor receptor 3 expression in several human cell lines, however, cell culture examples are generally not predictive of *in vivo* inhibition and the methods of delivery of the exemplified cell line would not be applicable to delivery of oligonucleotides to any organism. Often formulations and techniques for delivery *in vitro* (cell culture) are not applicable *in vivo* (whole organism) (see for example Jen et al., page 313, second column, second paragraph). For example, Agrawal et al. (see p 79-80, section entitled

"Cellular uptake facilitators for *in vitro* studies") states "The cellular uptake of negatively charged oligonucleotides is one of the important factors in determining the efficacy of antisense oligonucleotides.....*In vitro*, cellular uptake of antisense oligonucleotides depends on many factors, including cell type, kinetics of uptake, tissue culture conditions, and chemical nature, length and sequence of the oligonucleotide. Any one of these factors can influence the biological activity of an antisense oligonucleotide." Due to differences in the physiological conditions of a cell *in vitro* versus *in vivo*, the uptake and biological activity observed *in vitro* would not predictably translate to *in vivo* results.

13. Given these teachings, the skilled artisan would not know *a priori* whether introduction of antisense oligonucleotides *in vivo* by the broadly disclosed methodologies of the instant invention, would result in successful inhibition of expression of a target gene. One of skill in the art would not know how to deliver oligonucleotides to an organism in such a way that would ensure an amount sufficient to modify or inhibit expression of a target gene is delivered to the proper cell.

14. In fact, the state of the art is such that successful delivery of oligonucleotide sequences *in vivo* or *in vitro*, such that the polynucleotide or oligonucleotide provides the requisite biological effect to the target cells/tissues/organs, must be determined empirically. Methods of inhibiting gene expression using nucleic acids *in vivo* are unpredictable with respect to delivery of the nucleic acid molecule such that the nucleic acid molecule is targeted to the appropriate cell/organ, at a bioeffective concentration

and for a period of time such that the nucleic acid molecule is effective in, as in the instant application, attenuating or inhibiting expression of a target gene.

15. The specification does not provide the guidance required to overcome the art-recognized unpredictability of using antisense oligonucleotides in therapeutic applications in any organism. The field of antisense therapeutics does not provide that guidance, such that the skilled artisan would be able to practice the claimed therapeutic methods.

16. Thus, while the specification is enabling for the examples set forth in the specification demonstrating inhibition of fibroblast growth factor receptor 3 in cultured cells *in vitro*, the specification is not enabling for antisense inhibition of the expression of fibroblast growth factor receptor 3 in cells or tissues of any organism *in vivo* as the art of inhibiting gene expression by introducing antisense oligonucleotides into an organism is neither routine nor predictable. In order to practice the claimed invention *in vivo* in all organisms a number of variables would have to be optimized, including 1). the mode of delivery of the antisense or oligonucleotide to an organism that would allow it to reach the targeted cell, 2). the amount of antisense or oligonucleotide that would need to be delivered in order to bind a sufficient amount of fibroblast growth factor receptor 3 to modulate gene expression once it reached the proper cell and 3). ensuring the antisense oligonucleotide remains viable in a cell for a period of time that allows modulation of gene expression to an extent that there is a measurable and significant effect. Each one of these variables would have to be empirically determined for each antisense oligonucleotide. While optimization of any single one of these steps may be

routine, when taken together the amount of experimentation required becomes such that one of skill in the art could not practice the invention commensurate in scope with the claims without undue, trial and error experimentation and therefore, claim 15 is not enabled.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2 and 4-14 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Bennett et al. (US 6,165,786, December 26, 2000).

17. Claim 1 is drawn to an oligonucleotide 8 to 50 bases in length that specifically hybridizes to the coding region of a nucleic acid that encodes fibroblast growth factor receptor 3 and inhibits the expression of fibroblast growth factor receptor 3. Claim 2 limits claim 1 by stating the oligonucleotide is an antisense oligonucleotide. Claims 4-10 limit claim 2 by stating the antisense oligonucleotide can comprise a modified linkage

that may be a phosphorothioate, a modified sugar moiety where the modification may be methoxyethyl, a modified nucleobase that may be 5-methylcytosine or can comprise a chimeric oligonucleotide. Claim 11 is directed to a compound 8 to 50 bases in length that specifically hybridizes to and inhibits at least 8 bases of a nucleic acid encoding fibroblast growth factor receptor 3. Claims 12-14 are drawn to a composition of the compound of claim 1 where the compound may be an antisense oligonucleotide and can further comprise a colloidal dispersion system.

18. Bennett et al. disclose antisense oligonucleotides targeted to nucleolin that include an oligonucleotide 20 bases long designated as SEQ ID NO: 42 that hybridizes to nucleotides 1353-1370 of the nucleic acid encoding fibroblast growth factor receptor 3. Bennett et al. disclose at column 6 line 12 through column 10, line 23 that antisense oligonucleotides targeted to nucleolin can comprise modified linkages including phosphorothioates, modified sugar moieties including methoxyethyl, modified nucleobases including 5-methylcytosine and that such oligonucleotides can be chimeras. At columns 17-20 Bennett et al. disclose that the oligonucleotides can be made into compositions with liposomes, a colloidal dispersion system and at column 23, lines 23-45 that the compositions are formed with pharmaceutically acceptable carriers. Although the oligonucleotide of Bennett et al. is not disclosed as specifically hybridizing to a nucleic acid molecule encoding fibroblast growth factor receptor 3, the oligonucleotide of Bennett et al. is the complement of nucleotides within SEQ ID NO: 10 of the instant application and would therefore be expected to "specifically hybridize" to a

nucleic acid encoding fibroblast growth factor receptor 3 as per applicant's definition set forth in the specification as filed, see page 12, lines 4-18.

19. Furthermore, since the prior art oligonucleotides meet all the structural limitations of the claims, the prior art oligonucleotides would then be considered to "inhibit expression" of the gene as claimed, absent evidence to the contrary. See, for example, MPEP 2112, which states "[w]here applicant claims a composition in terms of a function, property or characteristic and the composition of the prior art is the same as that of the claim but the function is not explicitly disclosed by the reference, the examiner may make a rejection under both 35 USC 102 and 103, expressed as a 102/103 rejection. 'There is nothing inconsistent in concurrent rejections for obviousness under 35 USC 103 and for anticipation under 35 USC 102' In re Best, 562 F.2d 1252, 1255 n.4, 195 USPQ 430, 433 n.4 (CCPA 1977). This same rationale should also apply to product, apparatus, and process claims claimed in terms of function, property or characteristic. Therefore, a 35 USC 102/103 rejection is appropriate for these types of claims as well as for composition claims."

20. Thus, Bennett et al. disclose all limitations of and anticipate claims 1, 2 and 4-14.

Claims 1, 2 and 4-14 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Monia et al. (US 6,140,124, October 31, 2000).

21. Claims 1, 2 and 4-14 are described in the previous 102 rejection. Monia et al. disclose antisense oligonucleotides targeted to p38 mitogen-activated protein kinase

that include an oligonucleotide 20 bases long designated as SEQ ID NO: 22 that hybridizes to nucleotides 2321-2340 of the nucleic acid encoding fibroblast growth factor receptor 3. Monia et al. disclose at column 6 line 55 through column 9, line 34 that antisense oligonucleotides targeted to p38 mitogen-activated protein kinase can comprise modified linkages including phosphorothioates, modified sugar moieties including methoxyethyl, modified nucleobases including 5-methylcytosine and that such oligonucleotides can be chimeras. At column 10, line 30 through column 11, line 14 Monia et al. disclose that the oligonucleotides can be made into compositions with pharmaceutically acceptable carriers and may contain liposomes, a colloidal dispersion system. Although the oligonucleotide of Monia et al. is not disclosed as specifically hybridizing to a nucleic acid molecule encoding fibroblast growth factor receptor 3, the oligonucleotide of Monia et al. is the complement of nucleotides within SEQ ID NO: 10 of the instant application and would therefore be expected to "specifically hybridize" to a nucleic acid encoding fibroblast growth factor receptor 3 as per applicant's definition set forth in the specification as filed, see page 12, lines 4-18.

22. Furthermore, since the prior art oligonucleotides meet all the structural limitations of the claims, the prior art oligonucleotides would then be considered to "inhibit expression" of the gene as claimed, absent evidence to the contrary. See, for example, MPEP 2112, which states "[w]here applicant claims a composition in terms of a function, property or characteristic and the composition of the prior art is the same as that of the claim but the function is not explicitly disclosed by the reference, the examiner may make a rejection under both 35 USC 102 and 103, expressed as a 102/103 rejection.

'There is nothing inconsistent in concurrent rejections for obviousness under 35 USC 103 and for anticipation under 35 USC 102' In re Best, 562 F.2d 1252, 1255 n.4, 195 USPQ 430, 433 n.4 (CCPA 1977). This same rationale should also apply to product, apparatus, and process claims claimed in terms of function, property or characteristic. Therefore, a 35 USC 102/103 rejection is appropriate for these types of claims as well as for composition claims."

23. Thus, Monia et al. disclose all limitations of and anticipate claims 1, 2 and 4-14.

Claims 1, 2 and 4-14 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Popoff et al. (US 6,187,587, February 13, 2001).

24. Claims 1, 2 and 4-14 are described in a previous 102 rejection. Popoff et al. disclose antisense oligonucleotides targeted to E2F transcription factor 1 that include an oligonucleotide 20 bases long designated as SEQ ID NO: 32 that hybridizes to nucleotides 620-637 of the nucleic acid encoding fibroblast growth factor receptor 3. Popoff et al. disclose at column 7 line 10 through column 11, line 10 that antisense oligonucleotides targeted to E2F transcription factor 1 can comprise modified linkages including phosphorothioates, modified sugar moieties including methoxyethyl, modified nucleobases including 5-methylcytosine and that such oligonucleotides can be chimeras. At columns 18-21 Popoff et al. disclose that the oligonucleotides can be made into compositions with liposomes, a colloidal dispersion system and at column 24, lines 6-49 that the compositions are formed with pharmaceutically acceptable carriers.

Although the oligonucleotide of Popoff et al. is not disclosed as specifically hybridizing to a nucleic acid molecule encoding fibroblast growth factor receptor 3, the oligonucleotide of Popoff et al. is the complement of nucleotides within SEQ ID NO: 10 of the instant application and would therefore be expected to "specifically hybridize" to a nucleic acid encoding fibroblast growth factor receptor 3 as per applicant's definition set forth in the specification as filed, see page 12, lines 4-18.

25. Furthermore, since the prior art oligonucleotides meet all the structural limitations of the claims, the prior art oligonucleotides would then be considered to "inhibit expression" of the gene as claimed, absent evidence to the contrary. See, for example, MPEP 2112, which states "[w]here applicant claims a composition in terms of a function, property or characteristic and the composition of the prior art is the same as that of the claim but the function is not explicitly disclosed by the reference, the examiner may make a rejection under both 35 USC 102 and 103, expressed as a 102/103 rejection. 'There is nothing inconsistent in concurrent rejections for obviousness under 35 USC 103 and for anticipation under 35 USC 102' In re Best, 562 F.2d 1252, 1255 n.4, 195 USPQ 430, 433 n.4 (CCPA 1977). This same rationale should also apply to product, apparatus, and process claims claimed in terms of function, property or characteristic. Therefore, a 35 USC 102/103 rejection is appropriate for these types of claims as well as for composition claims."

26. Thus, Popoff et al. disclose all limitations of and anticipate claims 1, 2 and 4-13.

Claims 1, 2 and 4-14 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Bennett et al. (US 6,335,194, January 1, 2002).

27. Claim 1, 2 and 4-14 are described in a previous 102 rejection. Bennett et al. disclose antisense oligonucleotides targeted to survivin that include an oligonucleotide 20 bases long designated as SEQ ID NO: 235 that hybridizes to nucleotides 3458-3477 of the nucleic acid encoding fibroblast growth factor receptor 3. Bennett et al. disclose at columns 6-9 that antisense oligonucleotides targeted to survivin can comprise modified linkages including phosphorothioates, modified sugar moieties including methoxyethyl, modified nucleobases including 5-methylcytosine and that such oligonucleotides can be chimeras. At column 14, lines 11-64 Bennett et al. disclose that the oligonucleotides can be made into compositions with pharmaceutically acceptable carriers that may contain a colloidal dispersion system. Although the oligonucleotide of Bennett et al. is not disclosed as specifically hybridizing to a nucleic acid molecule encoding fibroblast growth factor receptor 3, the oligonucleotide of Bennett et al. is the complement of nucleotides within SEQ ID NO: 10 of the instant application and would therefore be expected to "specifically hybridize" to a nucleic acid encoding fibroblast growth factor receptor 3 as per applicant's definition set forth in the specification as filed, see page 12, lines 4-18.

28. Furthermore, since the prior art oligonucleotides meet all the structural limitations of the claims, the prior art oligonucleotides would then be considered to "inhibit expression" of the gene as claimed, absent evidence to the contrary. See, for example,

MPEP 2112, which states "[w]here applicant claims a composition in terms of a function, property or characteristic and the composition of the prior art is the same as that of the claim but the function is not explicitly disclosed by the reference, the examiner may make a rejection under both 35 USC 102 and 103, expressed as a 102/103 rejection. 'There is nothing inconsistent in concurrent rejections for obviousness under 35 USC 103 and for anticipation under 35 USC 102' In re Best, 562 F.2d 1252, 1255 n.4, 195 USPQ 430, 433 n.4 (CCPA 1977). This same rationale should also apply to product, apparatus, and process claims claimed in terms of function, property or characteristic. Therefore, a 35 USC 102/103 rejection is appropriate for these types of claims as well as for composition claims."

29. Thus, Bennett et al. disclose all limitations of and anticipate claims 1, 2 and 4-14.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tracy Vivlemore whose telephone number is 571-272-2914. The examiner can normally be reached on Mon-Fri 8:45-5:15.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on 571-272-0760. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance.

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Tracy Vivlemore
Examiner
Art Unit 1635

TV
February 14, 2005

SEAN McGARRY
PRIMARY EXAMINER
1635